UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,929	08/04/2003	David Wallach	WALLACH10D	4943

1444 7590 01/29/2008

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,929	WALLACH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 11/01/2007, has been entered.

Claims 1 and 6 have been amended.

Claims 2-5 have been canceled previously.

Claims 1 and 6 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's amendment, filed 11/01/2007.

The rejections of record can be found in the previous Office Action.

3. Priority.

Upon reconsideration of applicant's amended claims, it appears that the effective priority date of the instant claims appears to be the filing date of priority application USSN 07/524,263, filed 05/16/1992.

It does not appear that the foreign priority application IL 091229, filed 08/06/1989, provides sufficient written description for the claimed limitations of
"residues 27-214 of SEQ ID NO: 3)",
determining the level of TBP-II "in a subject", and
"comparing the level so determined with the normal levels of TBP-II in human body fluids of healthy subjects, wherein a level above said normal level indicates over-production of TBP-II and a level below said normal level indicates under-production of TBP-II".

If applicant desires priority prior to 05/16/1992,
applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. 112, first paragraph.

The examiner appreciates the provision of foreign priority application IL 091229.

For the record, applicant is reminded that the proper number for the priority document is USSN 07/524,263 and not USSN 07/534,263 as sometimes indicated in the Remarks, filed 11/01/2007.

It is noted that the priority on the first page of the instant specification properly indicates USSN 07/524,263.

4. Upon reconsideration of applicant's amended claims and arguments,
the previous rejections under 35 U.S.C. § 112, second paragraph, has been withdrawn.

5. Upon reconsideration of applicant's amended claims and arguments,
the previous rejection under 35 U.S.C. 112, first paragraph, enablement has been withdrawn.

6. Upon reconsideration of applicant's amended claims and arguments,
the previous rejection under 35 U.S.C. 112, first paragraph, written description has been withdrawn.

7. Given that the effective priority date of the instant claims appears to be the filing date of priority application USSN 07/524,263, filed 05/16/1992 for the reasons above in section under Priority,
the prior art rejections of record are maintained.

A claim as a whole has only one effective filing date.
See e.g. Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Therefore, applicant's arguments, filed 11/01/2007, based upon having a priority date of the priority document IL 091229, filed 08/06/1989, have been fully considered but have not been found convincing.

8. Claims 1 and 6 are rejected under 35 U.S.C. § 102(a)(b) as being anticipated by Brockhaus et al. (EP 0334165, published 09/27/1989) (see entire document) for the reasons of record.

Applicant's arguments, filed 11/01/2007, based upon having a priority date of the priority document IL 091229, filed 08/06/1989, have been fully considered but have not been found convincing for the reasons indicated above in Sections 3 and 7.

The following is reiterated for applicant's convenience.

Brockhaus et al. teaches antibodies to TNF receptor (see columns 3-6, Examples and Claims) and their use as diagnostic tools for the determination of TNF receptors on the cell surface and of soluble forms, including tissues samples with assays well known in the art (see columns 5-6, overlapping paragraph and Claim 21).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations of measuring the interaction of TBP-II with TBP-II-specific antibodies and determining said levels in comparison to normal values would be inherent properties of the referenced methods to detect TNF receptors in cells and tissues in diagnostic assays.

Although the reference does not explicitly indicated that one compares levels with normal values, such assays required comparison to normal values for proper analysis. Therefore, the ordinary artisan would have immediately envisaged carrying out immunoassays with controls and in the case with diagnostic assays, normal and healthy human values were employed as the proper controls and comparison for determining values that are either above or below the values observed in normal healthy individuals at the time the invention was made.

There does not appear to be any manipulative differences between the prior art disclosure and the instant methods.

Although the prior art does not disclose the terminology TBP-II or SEQ ID NO: 3 per se, it appears that the prior art and the instant claims are drawn to the same p75 tumor necrosis factor receptors.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced tumor necrosis factor binding proteins or receptors.

9. Claims 1 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brockhaus et al. (EP 0334165, published 09/2719/89) in view of Wolpe et al. (U.S. Patent No. 5,700,466) (see entire document) for the reasons of record.

Applicant's arguments, filed 11/01/2007, based upon having a priority date of the priority document IL 091229, filed 08/06/1989, have been fully considered but have not been found convincing for the reasons indicated above in Sections 3 and 7.

The following is reiterated for applicant's convenience.

Brockhaus et al. (EP 0334165) teach antibodies to TNF receptor (see column 3, paragraph 5; column 9, paragraphs 4-5, Example 3) and their use as diagnostic tools for the determination of TNF receptors on the cell surface and of soluble forms, including tissues samples with assays well known in the art (see columns 5-6, overlapping paragraph and Claim 21) (see entire document).

Although the prior art does not disclose the terminology TBP-II or SEQ ID NO: 3 per se, it appears that the prior art and the instant claims are drawn to the same p75 tumor necrosis factor receptors.

Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced tumor necrosis factor binding proteins or receptors.

Brockhaus et al. (EP 0334165) differs from the claimed invention by not disclosing comparing the over-production and under production of TBP-II in immunoassays to detect tumor necrosis factor binding proteins.

In addition, Wolpe et al. (U.S. Patent No. 5,700,466) (see entire document) has been added to provide further evidence that diagnostic assays, including those associated with TNF and related diseases, were well known and practiced at the time the invention was made. For example, Wolpe et al. indicates that the use of antibodies for diagnosis purposes has been extensively described in the literature (e.g., see column 7, lines 20-22).

Although the references do not explicitly indicated that one compares levels with normal values, such assays required comparison to normal values for proper analysis. Therefore, the ordinary artisan would have immediately envisaged carrying out immunoassays with controls and in the case with diagnostic assays, normal and healthy human values were employed as the proper controls and comparison for determining values that are either above or below the values observed in normal healthy individuals at the time the invention was made.

Given the role of TNF and/or cellular /soluble TNF receptors in various disease conditions as taught by the prior art, one of ordinary skill in the art at the time the invention was made would have been motivated to select TNF-receptor-specific antibodies for various immunoassays well known in the art to detect and determine the levels TNF receptors in various tissues and body fluids to determine their presence in various disease conditions as well as to monitor the effectiveness of treatment of said diseases, as taught by Wolpe et al. (e.g., see column 6, paragraph 3 – column 7) and Brockhaus et al. (see columns 5-6, overlapping paragraph and Claim 21). The ordinary artisan would have had an expectation of success in determining levels of TNF receptors in the various tissues and body fluids, given the prior art teachings of detecting TNF and TNF receptors and the presence of said molecules in certain disease conditions.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. , 2007 U.S. LEXIS 4745, 2007 WL 1237837, at *12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to determine the expression of TNF receptors in disease conditions as well as during the treatment of said disease conditions, determining the under-expression or the over-expression of TNF receptors and comparing such values to normal healthy individuals was routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such immunoassays for detecting TNF receptors.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary

10. Claims 1 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brockhaus et al. (EP 0334165, published 09/2719/89) in view of Wolpe et al. (U.S. Patent No. 5,700,466)
as applied to claims 1 and 6 above and further in view of
Brockhaus et al. (U.S. Patent No. 5,610,279) (see entire document) for the reasons of record.

Applicant's arguments, filed 11/01/2007, based upon having a priority date of the priority document IL 091229, filed 08/06/1989, have been fully considered but have not been found convincing for the reasons indicated above in Sections 3 and 7.

The following is reiterated for applicant's convenience.

Brockhaus et al. (EP 0334165, published 09/2719/89) in view of Wolpe et al. (U.S. Patent No. 5,700,466) has been taught above.

Brockhaus et al. (U.S. Patent No. 5,610,279) has been added to provide more evidence for the structure of the TNF binding proteins of the prior art, including a clearer indication of the p75 tumor necrosis factor receptor that reads on the instant TBP-II, than a reading of Brockhaus et al. (EP 0334165) may indicate.

Brockhaus et al. (U.S. Patent No. 5,610,279) teaches the structure of the p75 tumor necrosis factor that reads on the instant TBP-II, including providing a nucleotide sequence and a deduced amino acid sequence for the cDNA (e.g., see Detailed Description, Examples and Figure 4).

Further, Brockhaus et al. (U.S. Patent No. 5,610,279) teaches antibodies to TNF receptor (see columns 3-6, Examples and Claims) and their use as diagnostic tools for the determination of TNF receptors on the cell surface and of soluble forms, including tissues samples with assays well known in the art (see columns 5-6, overlapping paragraph and Claim 21) (see entire document).

For the reasons above, the ordinary artisan had both the motivation and expectation of success in determining levels of TNF receptors in the various tissues and body fluids, given the prior art teachings of detecting TNF and TNF receptors and the presence of said molecules in certain disease conditions. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary

10. No claim allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
January 22, 2008